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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,791	08/08/2001	David Hung	05284.00130	9920

22907 7590 09/09/2003

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 09/09/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,791

Applicant(s)

HUNG, DAVID

Examiner

Ulrike Winkler

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

The Amendment filed July 21, 2003 (Paper No. 11) in response to the Office Action of April 29, 2003 is acknowledged and has been entered. Claims 3,4,16, 21 and 22 have been cancelled. Claims 1, 2, 5-15, 17-20 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Drawings

The drawings are objected to, please see Notice of Draftsperson's Review attached to the instant Office Action.

Specification

The office acknowledges the amendment to the specification removing the the embedded hyperlink and/or other form of browser-executable code (<http://>) according to MPEP § 608.01.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 2, 5-15, 17-20 under 35 U.S.C. 103(a) as being unpatentable over Love et al. (U.S.Pat. No. 6,221,622, IDS) in view of Sukumar et al. (U.S. Pat. No. 5,763,415), Makita et al. (Breast Cancer Research, 1991, IDS), King et al. (JNCI, 1983, IDS), Noguchi et al. (American Journal of Pathology 1994), Gross G. (Intervirology 1997) and Androphy (Ciba Found. Symposium, 1986) is **maintained** for reasons of record.

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Applicant's arguments have been fully considered but are not deemed fully persuasive. Applicant's arguments are that the claimed subject matter is drawn to (1) retrieving the fluid through the same lumen and (2) that none of the secondary references disclose the use of a single lumen catheter for the extraction of breast fluid samples.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the same lumen) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The amended claims are drawn to obtaining fluid through an access tool having "at least one lumen" and "retrieving through at least one lumen", the limitation of having at least one does not preclude the use of an access tool having more than one lumen. Therefore, applicant's arguments are not persuasive.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, applicant arguments are that none of secondary references are anticipatory references. As the rejection was made under 35 U.S.C. 103(a) the secondary references are to show what is known in the art in general regarding the presence of papillomavirus in the breast duct tissue.

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To reiterate, the prior art establishes that it was known to introduce/extract washing fluids using a dual lumen catheter. The prior art established that it was known to introduce therapeutic agents into the breast duct directly. It was also knownⁱⁿ the prior art that papillomavirus lesion were found in the breast duct. Based on what was known in the prior art at the time the invention was made it would have been obvious to one of ordinary skill in the art to (1) utilize a duct washing system for the diagnosis of the presence of a viral agent in the breast duct and (2) utilize a duct washing system for the diagnosis of the presence of a viral agent followed by the introduction of an antiviral agent to the patient. One having ordinary skill in the art would have been motivated to use the cellular and non cellular material extracted by the dual lumen catheter as taught by Love in conjunction with assays for the presence of papillomavirus in the breast duct. Makita et al., King et al. and Noguchi et al. each establish that the presence of papillomavirus in the epithelial layers of the breast duct was known in the art. Optimizing the diagnostic condition with repeated sample analysis would be an obvious step to the ordinary artisan. If the timing of the monitoring step provides an unexpected result, applicant needs to point out what the unexpected results are. Applying a therapeutic antiviral agent to the breast duct would be obvious. Love teaches that a therapeutic agent can be applied using the double lumen catheter. Sukumar et al. teach the introduction of a composition into the breast duct, which destroys the epithelial tissue a primary site for papillomavirus infection. Androphy and Gross teach the use of interferon for the treatment of papillomavirus, the interferon can be administered directly to the papillomavirus lesion or it can be administered systemically. Optimizing the treatment condition would be an obvious step to the ordinary artisan.

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The prior art teaches that papilloma lesion are present in the breast duct, the prior art teaches the collection of fluid and cells from a breast duct for the purpose of determining the presence of papillomavirus by cytochemical and histochemical analysis. The prior art teaches treatment of papillomavirus by administering the interferon to a patient either topically or systemically. Therefore, taken what was known in the prior art as a whole it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to identify the presence of papillomavirus in a single breast duct and apply treatment to the single breast duct.

The rejection is maintained.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294.

The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


ULRIKE WINKLER, PH.D. 9/15/03
PATENT EXAMINER